



**UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/628,345	07/28/00	CAVAZZA	C 2801-21

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HM22/0828

EXAMINER

KIM, J

ART UNIT

PAPER NUMBER

1617

DATE MAILED:

08/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/628,345

Applicant(s)

CAVAZZA, CLAUDIO

Examiner

Jennifer M Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 8 and 12-18 is/are pending in the application.
- 4a) Of the above claim(s) 1-4, 8 and 12-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5 and 15-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Response to Amendment

The amendment filed on 7/02/2001 has been entered. New claims 16-18 have been added.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 5 and 15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 6,180,680 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because it encompasses same subject matter.

Responses to Arguments

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Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's admission for the reasons set forth in the office action mailed 1/21/2001.

Applicant's arguments filed 7/2/2001 have been fully considered but they are not persuasive.

Applicant asserts that while the effect of the statins generally and the effects of alkanoyl L-carnitines generally are known relative to lipid metabolism, but there is not suggestion in the art to combine these two or administer them in a coordinated manner to mitigate the potentially toxic or unwanted side effect-causing results of high dosage statins and thereby allow the clinician to use a lower dose of the statin while achieving the same or substantially the same therapeutic benefit. Applicant argues that the prior art generally but fails to advance or cite any specific document that specifically describe or discloses the use of an alkanoyl L-carnitine in combination with a statin.

This is not persuasive since as Applicant admitted by the Applicant that the general effect of the statins and the general effects of alkanoyl L-carnitines are known relative to lipid metabolism, therefore it would have been obvious to skilled artist to combine both active agents to achieve a least additive effect in treatment of lipid metabolism.

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The motivation for combining the components flows from their individually known common utility (see *In re Kerkhoven*, 205 USPQ 1069(CCPA 1980)).

Therefore, Applicant's admission alone is sufficient to support general knowledge of individual effect of active agent in lipid metabolism.

The data has been carefully reviewed, and it supports the synergism of simvastatin and propionyl L-carnitine. However, there of no "evidence" to support of synergism of other alkanoyl L-carnitine and other statin set forth in Applicant's claims.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

In view of the above Office Action of 1/12/2001 is deemed proper and asserted with full force and effect herein to obviate applicants' claims.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 5, 15, and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's admission.

Applicant admits at page 2, lines 11-20 that the statins including simvastatin reduce the hepatic synthesis of cholesterol.

Applicant also admits at page 3, line 22 through page 4, line 1, that the antitriglyceridaemic and anticholesterolameic effect of a number of **alkanoyl** carnitines are well known.

The claims differ from the cited references in claiming combination of alkanoyl carnitine such as propionyl L-carnitine and simvastatin to treat disorders associated with abnormal lipid metabolism. To incorporate propionyl L-carnitine with simvastatin to treat disorders associated with abnormal lipid metabolism would have been obvious because the antitriglyceridaemic and anticholesterolameic effect of a number of **alkanoyl** carnitines are well known. It would be expected that the combination of any **alkanoyl** carnitines with simvastatin components would lower lipid conditions as well.

The skilled artist would have been motivated to combine above active agents with reasonable expectation of success to treat disorders associated with abnormal lipid metabolism since both active claimed known agents have same physiological activity.

Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

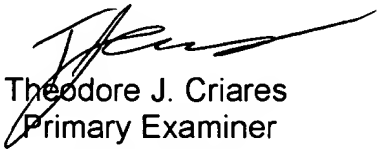
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is (703) 308-2232. The examiner can normally be reached on Monday through Friday from 9 AM. to 4 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


Theodore J. Criares
Primary Examiner
Art Unit 1617

jmk
August 21, 2001